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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional): 704652-9001

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]

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Application Number	Filed
10/606,745	June 27, 2003

First Named Inventor: Gluckman, P.

Art Unit	Examiner
1654	Russel, J.

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- [ ] applicant/inventor.
- [ ] assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- [X] attorney or agent of record. Registration number 36,113
- [ ] attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

Sharon E Crane
Signature

Sharon E. Crane, Ph.D.
Typed or printed name

202-373-6000
Telephone number

October 22, 2007
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

[X] *Total of _____ forms are submitted.

Attorney's Docket No.: 704652-9001

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of	**MAIL STOP AF**
Peter Gluckman *et al.*	Group Art Unit: 1654
Application No.: 10/606,745	Examiner: Jeffrey E. RUSSEL
Filed: June 27, 2003	Confirmation No.: 5345
For: IGF-1 TO IMPROVE NEURAL OUTCOME (As Amended)	**MAIL STOP AF**

PRE-APPEAL BRIEF REQUEST FOR REVIEW

The instant application is a reissue application for U.S. Patent No. 5,714,460 ("the '460 patent"). In response to the Office Action mailed July 20, 2007 (twice rejecting claims in this application), Applicants submit this Pre-Appeal Brief Request for Review to address the substantive rejections of the claims. Applicants will address the remaining issues following resolution of the substantive rejections addressed below.

Clear Errors in the Examiner's Rejections

Applicants submit that it is clear error: (1) to reject Claims 16, 28, 66, 67, 72, and 73 under 35 U.S.C. § 103 "as being estopped on the merits by final judgment in Interference No. 104,533" and (2) to reject Claims 16, 28, 66, 67, 72, and 73 under 35 U.S.C. §§ 102(g) and/or 103 "as being estopped on the merits by final judgment in Interference No. 104,533." *See Office Action mailed July 20, 2007, Pages 4-6, ¶¶ 8-9.*

I. Interference Estoppel Under 35 U.S.C. § 103 – Claims 16, 28, 66, 67, 72, and 73

Claims 16, 28, 66, 67, 72, and 73 were rejected under 35 U.S.C. § 103 as purportedly estopped on the merits by final judgment in Interference No. 104,533. *Office Action mailed July 20, 2007, Pages 4-5, ¶ 8.* This rejection is respectfully traversed.

Examiner's Rejection

According to the Examiner,

> In the section of the interference count which corresponds to claim 1 of U.S. Patent No. 5,714,460, damaged glia or other non-cholinergic cells are treated with IGF-1 or biologically active analogues thereof. The interference count does not recite that the CNS injury predominantly affects glia. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to treat glial cells damaged by CNS injury which predominantly affects glia, because the interference count specifically recites that injured glia cells are to be treated, and the lack of injury to other types of cells would not have been expected to interfere with the ability of IGF-1 and its analogues to treat injured glia cells. With respect to claims 66, 67, 72, and 73, these claims recite the same or broader limitations as are recited in claims 8-9 of the '460 patent, which were designated as corresponding to the count. Gluckman filed a motion in the interference contesting

> the designation of this claim as corresponding to the count, which motion was denied (see pages 24-26 of the Decision on Motions). Accordingly, claims 66, 67, 72, and 73 are deemed obvious over that section of the count which corresponds to claim 1 of U.S. Patent No. 5,714,460. See 37 CFR 41.127(a) and MPEP 2308.03, Examples 2 and 3 (Rev. 4, October 2005). In the paper titled 'Notice Under 37 C.F.R. §1.178(b)' filed June 27, 2003, Applicants refer to footnote 17 of the Decision on Motions in the interference as indicating that Applicants would not be estopped from pursuing in a reissue application narrower claims that would not have been obvious in view of the lost count. However, the basis for this approach is that the reissue claims must be nonobvious over the lost count. As indicated above, the current reissue claims remain obvious over the lost count.

Office Action mailed July 20, 2007, Pages 4-5, ¶ 8.

Applicants' Response

During the course of Interference 104,533, the Count was Gluckman Claim 1 from the '460 patent OR Gluckman Claim 1 of U.S. Patent No. 5,861,373 OR Lewis Claim 129 from U.S. Patent Application Serial No. 09/064,159 OR Lewis Claim 135 of U.S. Patent Application Serial No. 09/318,001. *Decision on Motions in Interference 104,533, Paper No. 111, ¶¶ 1-5, 12, 13.* During Interference 104,533, the Count was given its broadest reasonable construction. *Decision on Motion in Interference 104,533, Paper No. 111, Page 40.* The Board noted that the "broadest reasonable construction of Gluckman's 460 claim 1 and 373 claim 1 is that the treatment must be for a CNS insult 'affecting' glia or other non-cholinergic cells, but may also affect cholinergic neurons." *Id.* The finding by the Board that Gluckman's claimed method could unintentionally also treat cholinergic cells was the basis for its denial of Gluckman's motion, referenced in the quote above by the Examiner.

In contrast, Applicants' Claims 16, 28, 66, 67, 72, and 73 are directed to the treatment of CNS injury wherein the CNS injury *predominantly affects glia.* **As noted in the Decision on Motions in Interference 104,533, "neither party discloses a *targeted treatment* in a patient of *one type of CNS cell to the exclusion of other CNS cells.*"** *Decision on Motions in Interference 104,533, Paper No. 111, ¶ 26* (emphases added). Applicants respectfully submit that the Count from Interference 104,533 does not render obvious Applicants claims which now specifically require that the CNS injury *predominantly affects glia.* That is, Applicants Claims 16, 28, 66, 67, 72, and 73 provide the "targeted treatment in a patient of one type of CNS cell to the exclusion of other CNS cells" that the Board found absent from the '460 patent.

Moreover, a party cannot seek to add a claim to an application in interference and request that it be designated as not corresponding to the Count. *L'Esperance v. Nishimoto*, 18 U.S.P.Q.2d 1534 (Bd. Pat. App. & Int. 1991). **The Decision on Motions from Interference 104,533 notes that because Gluckman could *not* add narrower claims, such as Claims 16, 28, 66, 67, 72, and 73, Gluckman would *not be estopped* from filing a reissue application seeking narrower claims that would not have been obvious in view of the subject matter of the lost count to the extent Gluckman's specification supports such claims.** *Decision on Motions in Interference 104,533, Paper No. 111, Page 23, Page 23, n.17* (emphasis added). Thus, rejection of Claims 16, 28, 66, 67, 72, and 73 due to purported interference estoppel is inappropriate because Gluckman was not permitted to add such claims during the interference and the Board specifically noted in its Decision that Gluckman *could* pursue such claims in a reissue application. *Id.*[1] Moreover, Examiner Russel failed to cite any basis other than his own opinion as to why the targeted glial cells would be obvious over a Count construed as treating any and all CNS cells.

Accordingly, Applicants respectfully request withdrawal of the rejection of Claims 16, 28, 66, 67, 72, and 73 under 35 U.S.C. § 103 due to interference estoppel.

II. Interference Estoppel Under 35 U.S.C. §§ 102(g) and/or 103 – Claims 16, 28, 66, 67, 72, and 73

Claims 16, 28, 66, 67, 72, and 73 were similarly rejected under 35 U.S.C. §§ 102(g) and/or 103 as being estopped on the merits by final judgment in Interference No. 104,533. *Office Action mailed July 20, 2007, Pages 5-6, ¶ 9.* This rejection is respectfully traversed.

Examiner's Rejection

According to the Examiner,

> In the section of the interference count which corresponds to claim 1 of U.S. Patent No. 5,714,460, damaged glia or other-non-cholinergic cells are treated with IGF-1 or biologically active analogues thereof. With respect to claims 16, 28, 66, 67, 72, and 73, these claims recite the same or broader limitations as is recited in claims 8-9 of the '460 patent, which were designated as corresponding to the count. Gluckman filed a motion in the interference contesting the

[1] With regard to support for Claims 16, 28, 66, 67, 72, and 73, on Pages 7 and 8 of Applicants' Amendment and Reply To Accompany Request For Continued Examination ("RCE") Pursuant To 37 C.F.R. § 1.114, filed June 28, 2007, Applicants set forth where in the application support may be found for each claim.

designation of this claim as corresponding to the count, which motion was denied (see pages 24-26 of the Decision on Motions). Further, Applicants' specification at column 1, lines 44-46, acknowledges that multiple sclerosis is a disease of the CNS which causes the loss of oligodendrocytes (which are a type of glia cells). This section of Applicants' specification is quoted in section [19] of the Decision on Motions. See also section [93] of the Decision on Motions. Accordingly, the count, which suggests treating glial cells which are injured by multiple sclerosis, also suggests the broader limitation of treating glial cells damaged by CNS injury which predominantly affects glia. Claims 16, 28, 66, 67, 72, and 73 are deemed obvious over that section of the count which corresponds to claim 1 of U.S. Patent No. 5,714,460. See 37 CFR 41.127(a) and MPEP 2308.03, Examples 2 and 3 (Rev. 4, October 2005). In the paper titled 'Notice Under 37 C.F.R. §1.178(b)' filed June 27, 2003, Applicants refer to footnote 17 of the Decision on Motions in the interference as indicating that Applicants would not be estopped from pursuing in a reissue application narrower claims that would not have been obvious in view of the lost count. However, the basis for this approach is that the reissue claims must be nonobvious over the lost count. As indicated above, the current reissue claims remain obvious over (or even anticipated by) the lost count.

Office Action mailed July 20, 2007, Pages 5-6, ¶ 9.

Applicants' Response

With regard to this rejection, Applicants reiterate their arguments made in response to the rejection of Claims 16, 28, 66, 67, 72, and 73 in the preceding section. Applicants submit that the Count from Interference 104,533 does not anticipate nor render obvious Claims 16, 28, 66, 67, 72, and 73 which now specifically require that the CNS injury *predominantly affects glia.*

With regard to the Examiner's citation of 37 C.F.R. § 41.127(a) in both rejections, Applicants submit that this portion of the Code simply states that an interference judgment "disposes of all issues that were, or by motion could have properly been, raised and decided." *37 C.F.R. § 41.127(a).* As explained above and as noted in footnote 17 on Page 23 of the Decision on Motions, Applicants could *not* have presented narrower claims, such as Claims 16, 28, 66, 67, 72, and 73, during the interference. Therefore, 37 C.F.R. § 41.127(a) does not apply to Applicants' situation.

With regard to the Examiner's citation of Examples 2 and 3 of M.P.E.P. § 2308.03, Applicants submit that these Examples are similarly inapplicable, but that M.P.E.P. § 2308.03 itself is instructive. The first paragraph of M.P.E.P. § 2308.03 notes that the "time for the party to make all pertinent arguments is during the interference, *unless the Board expressly prevented the party from litigating the issue during the interference.*" Here, the Board expressly prevented Applicants from presenting Claims 16, 28, 66, 67, 72, and 73 during the interference. *Decision on Motions in Interference 104,533, Paper*

No. 111, Page 23, Page 23, n.17. Yet, the Board also expressly noted in the Decision that Applicants would *not* be estopped from filing a reissue application seeking narrower claims that would not have been obvious in view of the subject matter of the lost Count. *Id.*

With regard to Example 2 in M.P.E.P. § 2308.03, this Example is inapplicable to Applicants' situation because it involves situations where the applicant files a continuation application with a "claim generic to subject matter X [the subject matter of the Count]." Applicants' Claims 16, 28, 66, 67, 72, and 73 are not generic to the Count in Interference 104,533, but are instead directed to methods for treating glial cells damaged from CNS injury, wherein said CNS injury *predominantly affects glia.*

With regard to Example 3 in M.P.E.P. § 2308.03, this Example is inapplicable to Applicants' situation because it involves situations where the applicant files a continuing application with a "claim to subject matter that would have been obvious in view of subject matter X [the subject matter of the Count]." Applicants' Claims 16, 28, 66, 67, 72, and 73 are not obvious in view of the subject matter of the Count in Interference 104,533, but are instead directed to methods for treating glial cells damaged from CNS injury, wherein said CNS injury *predominantly affects glia.* Indeed, Examiner Russel failed to cite any basis other than his own opinion as to why the targeted glial cells would be obvious over a Count construed as treating any and all CNS cells.

Accordingly, Applicants respectfully request withdrawal of the rejection of Claims 16, 28, 66, 67, 72, and 73 under 35 U.S.C. §§ 102(g) and/or 103 due to interference estoppel.

The Director is hereby authorized to charge any additional fees which may be required, or credit any overpayment, to Deposit Account No. 50-4047.

Respectfully submitted,
BINGHAM MCCUTCHEN, LLP

Date: October 22, 2007

By: Sharon E. Crane

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